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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/437,450

11/10/1999

JONATHAN H. FREEDMAN

1579-315

7992

7590

10/22/2002

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EXAMINER

PARAS JR, PETER

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 10/22/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/437,450

Applicant(s)

FREEDMAN ET AL.

Examiner

Peter Paras, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-19 is/are pending in the application.
- 4a) Of the above claim(s) 5,6,8-10, 12-14, and 16-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7,11 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 November 1999 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group III, claims 7, 11, and 15 in Paper No. 17 is acknowledged. The traversal is on the ground(s) that it would not be a serious burden to search the claims of Groups I-IV. In particular Applicants submit that it would not have been undue to search all the claims of Group I-IV as they are directed to nucleotide sequences that are differentially expressed from the gene. This is not found persuasive because it is maintained that each of Inventions I-IV requires a separate search status because the nucleotide sequences encompassed by the claims have different sequences. Since the nucleotide sequences encompassed by the claims have different sequences, they encode different proteins that have different functions. As such it is maintained that the different inventions require a different search status.

The requirement is still deemed proper and is therefore made FINAL.

Please note that after a final requirement for restriction, the Applicants, in addition to making any response due on the remainder of the action, may petition the Commissioner to review the requirement. Petition may be deferred until after final action on or allowance of claims to the invention elected, but must be filed not later than appeal. A petition will not be considered if reconsideration of the requirement was not requested. (See § 1.181.).

Claims 5-6, 8-10, 12-14, and 16-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no

allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 17.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 7, 11, and 15 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The claims are directed to an isolated nucleic acid comprising the sequence of DDRT16 (SEQ ID NO: 40) as well to the mRNA that it encodes. The claims are further directed to a transgenic *C. elegans* whose genome comprises the same nucleic acid sequence.

The claimed invention is directed to a nucleotide sequence that encodes cadmium-responsive gene isolated from *C. elegans*. The specification has asserted that the nucleotide sequence set forth in SEQ ID NO: 40 encodes a cadmium-responsive gene. The disclosed utilities for the nucleotide sequence set forth in SEQ ID NO: 40 include the diagnosis, prevention and treatment of diseases, creation of transgenic *C. elegans*, drug discovery, and as a biomonitor for cadmium toxicity.

However, the specification fails to provide a specific and substantial utility for the claimed nucleotide sequence or the polypeptide that it encodes. Neither the

specification nor any art of record teaches what the polynucleotide of SEQ ID NO: 40 does or, in the case of pharmaceutical compositions, establishes a relationship of the polynucleotide of SEQ ID NO: 40 to any specific disease or establishes any involvement of the polynucleotide of SEQ ID NO: 40 in the etiology of any specific disease, or establishes a nexus with a drug that may be used to prevent cadmium toxicity.

Although the specification has contemplated that the claimed sequence may be related to any of the diseases associated with cadmium toxicity (see pages 12-14), no evidence has been presented that relates the claimed sequence to even one such diseases.

A substantial utility is a utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities under §101. Applicant's specification fails to provide a "real world" use for the polypeptide encoded by SEQ ID NO: 40 such that the nucleic acid set forth in SEQ ID NO: 40 that encodes the unspecified protein additionally has no "real world" use. Neither the specification as filed, nor any art of record disclose or suggest any biological or biochemical activity for the protein encoded by SEQ ID NO: 40 such that any utility would be well established for the protein. The asserted utilities for SEQ ID NO:40 such as a probe for diagnosing a disease, primers for PCR, treatment of disease is merely a "potential" use that applies to any uncharacterized, unrelated polynucleotide sequences. Therefore the asserted utilities are not considered "specific" utilities, i.e. they are not specific to SEQ ID NO:40. The instant specification has not even provided an assertion of what protein SEQ ID NO: 40 may encode based on homology to other known sequences. Moreover, the specification has failed to

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provide evidence of any structural elements within the nucleotide sequence of SEQ ID NO: 40 that are generally related to other known nucleotide sequences. As such it is unclear what protein is encoded by the claimed sequence, what its function is, and what potential substrates it may act on. Furthermore, since neither the specification nor any art of record has taught what type of protein is encoded by SEQ ID NO: 40 the skilled artisan is left to speculate and investigate the uses of the uncharacterized protein. The specification essentially gives an invitation to experiment wherein the artisan is invited to elaborate a functional use for the disclosed nucleic acid and the protein that it encodes. In view of the lack of guidance with respect to the type of polynucleotide/protein the claimed invention encompasses, the skilled artisan would not know how to use the claimed nucleotide sequence or its expression product. Because the claimed invention is not supported by a specific asserted utility for the reasons set forth, credibility of any utility cannot be assessed.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7, 11, and 15 also rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

New Matter

Claim 15 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

Claim 15 is drawn to a *C. elegans* the genome of which has been engineered to include the nucleic acid sequence set forth in SEQ ID NO: 40.

The specification provides no implicit or explicit support for the context of the a *C. elegans* the genome of which has been engineered to include the nucleic acid sequence set forth in SEQ ID NO: 40. Applicants are reminded that it is their burden to show where the specification supports any amendments to the claims. See 37 CFR 1.121 (b)(2)(iii), the MPEP 714.02, 3rd paragraph, last sentence and also the MPEP 2163.07, last sentence.

MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition

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to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. *Applicant should therefore specifically point out the support for any amendments made to the disclosure* [or point to case law supporting incorporation of such a limitation as in the instant case]".

Conclusion

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at 703-305-4051. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703) 308-4242 and (703) 305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to Patsy Zimmerman whose telephone number is (703) 308-0009.

Peter Paras, Jr.

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